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May 18, 2020

VIA ECF
Honorable Tonianne J. Bongiovanni, U.S.M.J.
United States District Court for the District of New Jersey
Clarkson S. Fisher Federal Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

Re: *NewMarket v. VetPharm,* Civil Action No. 3:17-cv-01852-MAS-TJB

Dear Judge Bongiovanni:

We represent NewMarket Pharmaceuticals LLC ("NewMarket") in the above-referenced matter. We write to update the Court on the status of the recent arbitration between the parties per the Court's text order of March 13, 2020.

Since receiving the raw clinical trial data NewMarket has undertaken a painstaking evaluation process. This process has been especially cumbersome because VetPharm and Prelude Dynamics (the Electronic Data Capture company responsible for storing the electronic clinical trial data) refuse to make evaluation and reporting software available to NewMarket unless it pays thousands of dollars in fees.

Two things are clear based on NewMarket's on-going review of the clinical trial data that it did not have access to during the arbitration hearing. First, VetPharm misrepresented the efficacy of the study drug during the course of the study. Second, VetPharm failed to produce study-related information necessary to fully evaluate what went wrong with the study (*i.e.* the "*post-mortem*").

VetPharm Misrepresented the Efficacy of the Study Drug

During the arbitration VetPharm refused to produce information that would allow the efficacy of the study drug to be ascertained, namely (1) the lesion score and (2) whether or not the animal was on treatment or placebo. Instead of providing necessary data so that NewMarket could determine efficacy itself, VetPharm's Denni Day volunteered that the test drug "indicated a success rate of 86%."

Documents Necessary to Conduct the *Post-Mortem* Have Not Been Produced

The necessary information for NewMarket to conduct an effective *post-mortem* has not been produced. [redacted] Such a discrepancy could be explained by analyzing the shipping records of the test drug to each facility. If the study drug happened to be stored in an inappropriate location for an extended period of time, the study drug could have been compromised leading to ineffective results. This exemplary type of information is nowhere to be found in the materials provided to NewMarket by VetPharm. In fact, no information from study-vendors such as CSM, the entity responsible for preparing the clinical study supplies, has been included. Moreover, VetPharm refuses to permit NewMarket to obtain this information directly from study-vendors or to sign a straight-forward acknowledgement that NewMarket is entitled to any and all study-related materials from study vendors contracted by VetPharm.

NewMarket reserves all of its rights as it continues to review the clinical trial data, in the event information from subcontractors is made available to NewMarket, and when NewMarket gains access to the full databases including the evaluation and reporting software hosted by Prelude Dynamics. NewMarket respectfully requests a teleconference with the Court to discuss the above matters further. NewMarket will not withdraw the present action and instead will likely seek leave to amend its Complaint to add additional causes of action related to at least the issues described above at the appropriate time.

We thank the Court for its continued attention to this matter, and are available should Your Honor or Your Honor's staff require anything further or have any questions.

Respectfully submitted,

/s Joel A. Pisano

Joel A. Pisano

cc: All Counsel of Record (via ECF)